K 122764

DEC 2 8 2012

510(k) SUMMARY
Date Prepared: 04 Sep 2012

1. Company Name and Address

Medi-Physics Inc. dba GE Healthcare
3350 N Ridge Avenue
Arlington Heights, IL 60004

Contact Person: David Risley
Director, US Regulatory
Telephone (direct dial): 609-514-6489
Fax #: 609-514-6695
David.Risley@ge.com

2. Device Name

Proprietary Name: RAPID Strand Rx
Common Name: Radionuclide Brachytherapy Source

3. Classification

Radionuclide Brachytherapy Source has been classified by the Reproductive, Abdominal, and Radiological Devices Panel as Class II, 90-KXK. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Radionuclide Brachytherapy Source (21 CFR 892.5730).

4. Predicate Device

Medi-Physics Inc. RAPID Strand Rx
This 510(k), K063177, received FDA clearance on November 30, 2006.

5. Device Description

This Special 510(k) is for the addition of a loading services provider, addition of bone wax needle plugging material and removal of a seed design.

Medi-Physics Inc. has concluded that the device is substantially equivalent to the predicate device (RAPID Strand Rx, K063177), and is safe and effective for its intended use.

Indications for use for RAPID Strand Rx:

RAPID Strand ™ Rx is indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used either as primary treatment (such as for prostate cancer or unresectable tumors) or for treatment of residual disease after excision of the primary tumor.

RAPID Strand ™ Rx may be indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy.

Summary of Technological Characteristics Compared to Predicate Device

The product has the same intended use and fundamental scientific technology as the predicate device, RAPID Strand Rx (K063177).

The technological characteristics of the bone wax formulation were subject to design controls and risk management. All identified hazards have been sufficiently mitigated. A summary of results is enclosed. All the results are acceptable.

Conclusion:

Based on the above, Medi-Physics Inc. believes the RAPID Strand Rx is substantially equivalent to the predicate device, and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 28, 2012

C/O Mr. David Risley
Director, Quality, US Regulatory
Medi-Physics Inc. dba GE Healthcare
3350 N. Ridge Avenue
ARLINGTON HEIGHTS, IL 60004

Re: K122764
Trade/Device Name: RAPID Strand Rx
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: December 18, 2012
Received: December 19, 2012

Dear Mr. Risley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122764

Device Name: Rapid Strand Rx

Indications for Use:

RAPID Strand ™ Rx is indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used either as primary treatment (such as for prostate cancer or unresectable tumors) or for treatment of residual disease after excision of the primary tumor.

RAPID Strand ™ Rx may be indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)___K122764_____